approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TRISENOX (arsenic trioxide) injection, 1 mg/mL, is the subject of NDA 021248, held by Cephalon, Inc., and initially approved on September 25, 2000. TRISENOX is indicated in combination with tretinoin for treatment of adults with newly diagnosed low-risk acute promyelocytic leukemia (APL) whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression; and for induction of remission and consolidation in patients with APL who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.

In a letter dated February 21, 2018, the sponsor notified FDA that TRISENOX (arsenic trioxide) injection, 1 mg/mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated October 17, 2018 (Docket No. FDA–2018–P–3949), under 21 CFR 10.30, requesting that the Agency determine whether TRISENOX (arsenic trioxide) injection, 1 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TRISENOX (arsenic trioxide) injection, 1 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TRISENOX (arsenic trioxide) injection, 1 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TRISENOX (arsenic trioxide) injection, 1 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TRISENOX (arsenic trioxide) injection, 1 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs.

Dated: April 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–07828 Filed 4–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of COBRE Phase 1 Applications.

Date: July 10, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5215, Bethesda, MD 20892, (301) 435–2409, *grossmanrs@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 12, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–07750 Filed 4–17–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as Amended, Notice is Hereby Given of the Following Meetings

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Risk Prevention and Health Behavior AREA Review.

Date: May 30, 2019.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John H. Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 435–0628, *newmanjh@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Development, Risk and Prevention Study Section.

Date: June 6–7, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Anna L. Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, *rileyann@csr.nih.gov.*

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Cellular and Molecular Technologies Study Section.

Date: June 11–12, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Tatiana V. Cohen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 5213, Bethesda, MD 20892, 301–455–2364, *tatiana.cohen@nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: June 13, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Capital View, 2850 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Wenchi Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301–435–0681, *liangw3@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 12, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–07748 Filed 4–17–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2008–0010]

Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee Management; Request for Applicants for Appointment to the Board of Visitors for the National Fire Academy.

SUMMARY: The National Fire Academy (Academy) is requesting individuals who are interested in serving on the Board of Visitors for the National Fire Academy (Board) to apply for appointments as identified in this notice. Pursuant to the Federal Fire Prevention and Control Act of 1974, the Board shall review annually the programs of the Academy and shall make recommendations to the Federal Emergency Management Agency (FEMA) Administrator, through the United States Fire Administrator, regarding the operation of the Academy and any improvements that the Board deems appropriate. The Board is composed of eight members, all of whom have national or regional leadership experience in the fields of fire safety, fire prevention (such as community risk reduction to include wildland urban interface), fire control, research and development in fire protection, treatment and rehabilitation of fire victims, or local government services management, which includes emergency medical services. The Academy seeks to appoint three individuals to a position on the Board that will be open due to term expiration. If other positions are vacated during the application process, candidates may be selected from the pool of applicants to fill the vacated positions.

DATES: Resumes will be accepted until 11:59 p.m. EST May 20, 2019.

ADDRESSES: The preferred method of submission is via email. However, resumes may also be submitted by mail. Please only submit by ONE of the following methods:

- *Email: FEMA-NFABOV@fema.dhs.gov.*
- *Mail:* National Fire Academy, U.S. Fire Administration, Attention: Debbie Gartrell-Kemp, 16825 South Seton Avenue, Emmitsburg, Maryland 21727–8998.

FOR FURTHER INFORMATION CONTACT: *Alternate Designated Federal Officer,* Dr. Kirby Kiefer, telephone (301) 447–1083, email *Kirby.Kiefer@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Board is an advisory committee established in accordance with the provision of the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix. The purpose of the Board is to review annually the programs of the Academy and advise the FEMA Administrator on the operation of the Academy and any improvements therein that the Board deems appropriate. In carrying out its responsibilities, the Board examines Academy programs to determine whether these programs further the basic missions that are approved by the FEMA Administrator, examines the physical plant of the Academy to determine the adequacy of the Academy's facilities, and examines the funding levels for Academy programs. The Board submits a written annual report through the United States Fire Administrator to the FEMA Administrator. The report provides detailed comments and recommendations regarding the operation of the Academy.

Individuals who are interested in serving on the Board are invited to apply for consideration for appointment. There is no application form; however, a current resume and statement of interest will be required. The appointment shall be for a term of up to three years. Individuals selected for the appointment shall serve as Special Government Employees (SGEs), defined in section 202(a) of title 18, United States Code. The candidate selected for the appointment will be required to complete a Confidential Financial Disclosure Form (U.S. Office of Government Ethics (OGE) Form 450).

The Board shall meet as often as needed to fulfill its mission, but not less than twice each fiscal year to address its objectives and duties. The Board will meet in person at least once each fiscal year with additional meetings held via teleconference. Board members may be reimbursed for travel and per diem incurred in the performance of their duties as members of the Board. All travel for Board business must be approved in advance by the Designated Federal Officer. To the extent practical, Board members shall serve on any subcommittee that is established.

FEMA does not discriminate in employment on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disability and genetic information, age, membership in an employee organization, or other non-merit factor. FEMA strives to achieve a diverse candidate pool for all its recruitment actions.

Current DHS employees, contractors, and potential contractors will not be considered for membership. Federally registered lobbyists will not be considered for SGE appointments.

Terry Gladhill,

Branch Chief, National Fire Academy, United States Fire Administration, Federal Emergency Management Agency.

[FR Doc. 2019–07776 Filed 4–17–19; 8:45 am]

BILLING CODE 9111–45–P